

REMARKS

Independent claims 1 and 9 would not be anticipated by the disclosure of U.S. Patent No. 7,004,971 to Serhan et al (hereinafter Serhan). Serhan is in no way pertinent to a disk which is designed to replace a CMC joint and which, when surgically implanted between the metacarpus and the trapezium, is of such a character that each such bone will slide on the respective mating convex surface of the disk. Serhan shows a nucleus pulposus replacement, which is made of a material such as rubber or an elastomeric material having a defined compressive modulus so that the device will compress in response to a physiological axial load (see column 6, line 55 through column 7, line 6). Attached as Exhibit A is a copy of a portion of a page from Stedman's Medical Dictionary, 25th edition, which describes and illustrates Nucleus Pulposus, which is the soft fibril cartilage central portion of the intervertebral disk. It is a cushioning material that alternately compresses and expands (see column 9, lines 7-26). Although the elastomeric replacement ring of Serhan contains a central hole, in addition to not being a disk which provides two articular surfaces upon which bones can slide, it does not disclose a pair of convex spherical surfaces. The Serhan ring has an outer rim of toroidal surface shape, and at best it shows a pair of concave frustoconical surfaces that lead to the central hole. This is precisely the opposite of Applicant's claimed disk which has a pair of convex spherical surfaces which lead to the axial flaring hole. Reconsideration of the rejection of independent claims 1 and 9 based upon the elastomeric ring disclosed by Serhan for installation as a cushion in an intervertebral disk and withdrawal of that rejection are respectfully requested.

The subject matter of claim 7 is not anticipated by the disclosure of U.S. Patent No. 5,645,605 to Klawitter (hereinafter Klawitter). Method claim 7 is dependent upon claim 1 and thus requires the use of a biarticular disk of the precise construction recited in claim 1 and recites the reshaping of the surfaces of the metacarpus and the trapezium provide concave surfaces which match the convex surfaces of the disk. Klawitter teaches cutting a proper mortise groove in the trapezium (see column 6, line 30) that will receive a tenon 39 formed as a part of a trapezium element 14. The end of the metacarpus is resected and then broadched to provide an elongated cavity in the metacarpus to accept the stem of the other half of the two-part prosthesis.

It should be clear that Klawitter teaches nothing equivalent to a biarticular disk, and Klawitter certainly does not teach providing concave surfaces in the articulating surfaces of the metacarpus and trapezium to accept such a biarticular disk implant. The final sentence of Section 9 on page 4 of the Office Action appears to be an inadvertent carry-over from the earlier Office Action that misinterpreted the illustration of a torus in Figure 4, which was depicted simply to facilitate an understanding of the two mating surface shapes of the Klawitter two-piece CMC joint implant. The rejection of claim 7 based upon the disclosure of Klawitter should be reconsidered and withdrawn.

The methods recited in claims 15 and 16 would not be obvious to one of ordinary skill in the art from the disclosure of Serhan in view of the disclosure of Klawitter. With respect to claim 15, which is dependent upon claim 9, a circular disk having a pair of convex spherical surfaces is required; it is implanted between facing portions of two articulating bones that have been resected and shaped to create concave surfaces that allow sliding movement between the bones and respective mating convex surface of the disk, wherein there is an axial flaring opening that accommodates a flexible cord that has been passed through the passageways in the bones. As set forth above, Serhan does not disclose such a disk, and Klawitter does not teach resecting two articulating bones so as to provide concave surfaces that will accommodate a biarticular disk therebetween. Moreover, neither of them teaches creating passageways in the two bones leading to a central region of a concave surface shaped in that bone. Both are unconcerned with accommodating the use of a flexible cord. Claim 15 should be allowed.

With respect to claim 16, as previously pointed out, Serhan does not disclose a biarticular disk having a pair of convex spherical surfaces of the same spherical curvature as two resected surfaces in a base of the metacarpus and the distal surface of the trapezium. Klawitter does not disclose creating passageways in those two bones which lead to the resected concave surfaces thereof which would accommodate a flexible cord. As previously pointed out, the Klawitter two-piece device proposes a solution to the problem that is clearly an alternative to the use of the biarticular disk solution taught in the present application and claimed in claim 16. Certainly, there would be no motivation to combine the teaching of the use of an elastomeric ring-like cushion designed for placement in an intervertebral disk with the two-piece articulating bone

joint replacement of Klawitter. The rejection of claim 16 on this basis should be reconsidered and withdrawn.

With respect to claim 18 which positively recites the step of passing a flexible cord through passageways leading to the concave articular surfaces and the flaring axial hole in the disc, the Examiner adds the further reference to U.S. Patent No. 4,198,712 to Swanson (hereinafter Swanson). Swanson discloses a scaphoid implant which is intended to completely replace a small bone, i.e. the scaphoid 18 (see Fig. 1) in the hand/wrist of a patient. A concern of Swanson is to assure that the implanted bone remains in its intended operative position when the patient's hand is subsequently subjected to severe shocks and the like. One solution of Swanson is to stabilize the replacement scaphoid bone 40 (Fig. 2) by including a stabilizing stem 78 (see column 5, lines 14-28). The stem has a square cross section and is received in a cavity created in the trapezium 30 to in essence, rigidify these two small bones.

An alternative arrangement is disclosed in Figures 12-14 and described at column 6, lines 12-20. As an alternative to using the stemmed scaphoid implant 40 of Figs. 3-5, a passageway 102 is provided between two surfaces of the replacement scaphoid implant. This passageway is used to tie the scaphoid implant to an adjacent bone, i.e. the lunate 20. The operation is described at column 8, lines 15-39. A similar bore 122 is formed through the lunate bone, and a harvested tendon 120 is passed through the lunate bone and then looped around the scaphoid implant, entering and leaving the passageway 102 through two side surfaces of the scaphoid replacement 40. The tendon is then tied to itself alongside the side surface of the lunate. Careful study of the Swanson procedure will show that it is not being used to confine a biarticular disk between two bones nor does it pass through the centers of two resected concave surfaces in two articulating bones. Thus, although Swanson describes the use of a harvested tendon to broadly tie a complete replacement bone to an adjacent bone, it does not suggest routing a flexible cord or tendon directly through two articulating surfaces, particularly two surfaces that are now separated by a biarticular disk that is shaped so as to accommodate the flexible cord while at the same time facilitating articulation between the four respective surfaces despite the presence centrally thereof of the flexible cord. Accordingly, it is submitted that claim 18 is allowable not only for the reasons as set forth with respect to claim 16 (upon which it depends), but as

containing further recitations that would not be suggested by the disclosure of Swanson, which merely ties one replacement bone to an adjacent native bone along side surfaces thereof. Accordingly, the rejection of claim 18 and claims 19-20, which are dependent thereupon, should be reconsidered and withdrawn and these claims allowed.

With respect to page 9 of the Office Action, the present rejections of claims 7 and 15 are herein now specifically addressed. With respect to paragraph 24 of the Office Action, Klawitter does not teach the creation of passageways in the proximal bone of a digitus, and in the trapezium or other carpal or tarsal bone through which a flexible cord can be passed (see claim 9, for example). Klawitter resects the end of the trapezium and creates an open mortise groove therein while creating a blind cavity by broaching the intermedullary canal of the metacarpus. Neither of these openings would be equivalent to a passageway through which a flexible cord could be purposefully threaded. As explained above, careful examination of Figures 12-14 of Swanson will show that flexible cord does not pass through two surfaces that articulate with each other, and there is nothing in Swanson that would suggest to one that such a relationship would in any way be appropriate.

In view of the foregoing remarks, it is believed that independent claims 1, 9 and 15 and the claims dependent thereupon should be allowed, and allowance thereof is respectfully requested. It is believed that a Notice of Allowance allowing claims 1-20 is now appropriate, and favorable action is courteously solicited.

Date: January 21, 2009

Respectfully submitted,

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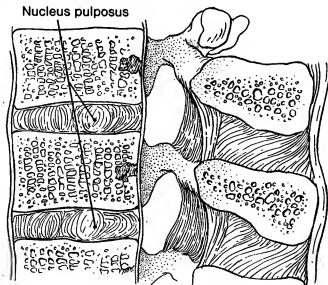
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n. preop'ticus latera'lis [NA], lateral preoptic n.; a vaguely defined group of nerve cells in the lateral zone of the preoptic region.
n. preop'ticus media'lis [NA], medial preoptic n.; a group of nerve cells forming the medial zone of the preoptic region.

prerubral n., the gray matter of field H₂; see *fields* of Forel.

n. pulpo'sus [NA], n. gelatinosus; vertebral pulp; the soft fibrocartilage central portion of the intervertebral disk; regarded as a derivative of the notochord.



Nucleus Pulposus

n. pyramida'lis, obsolete term for n. olivaris accessorius medialis.

pyrrole n., of porphyrins, a cyclic tetrapyrrole; four pyrrole groups joined into a ring structure by way of $-CH=$ (methylidyne) bridges between α (2) position of one pyrrole and α' (5) position of another pyrrole, the fourth pyrrole being joined to the first. See also porphin and porphyrin.

raphe nuclei, nuclei raphe.

nuclei raph'es, raphe nuclei; collective term denoting a variety of unpaired nerve cell groups in and along the median plane of the mesencephalic and rhombencephalic tegmentum: the n. centralis tegmenti superior, and the n. raphis dorsalis, n. raphis pontis, n. raphis magnus, n. raphe pallidus, and n. raphe obscurus. These nuclei include neurons characterized by their containing the indolamine transmitter agent serotonin; their serotonin-carrying axons extend rostrally to the hypothalamus, septum, hippocampus, and cingulate gyrus and include projections to brainstem, cerebellum, and spinal cord.

red n., n. ruber.

reduction n., a n. that degenerates in the cell during the changes incident to fertilization.

reproductive n., micronucleus (2).

reticular nuclei of the brainstem, the vaguely delineated cell groups composing the gray matter of the reticular formation of the rhombencephalon and mesencephalon. In general, large-celled territories occupy the medial two-thirds of the reticular formation: n. gigantocellularis medullae oblongatae, nuclei tegmenti pontis caudalis and oralis. Smaller groups of reticular nuclei are found laterally and in paramedian locations; lateral nuclei receive sensory collaterals and project medially; paramedian reticular nuclei largely project to the cerebellum. See also *formatio reticularis*.

n. reticula'ris thal'ami [NA], reticular n. of the thalamus; a sheet

rhombencephalic gustatory n., the rostral one-third of t. solitarius, receiving afferents from the facial, glossopharyngeal and vagus nerves conveying impulses originating from the taste buds.

Roller's n., (1) lateral n. of the accessory nerve; (2) a sn. n. lying immediately anterior to the hypoglossal n., consisting of the perihypoglossal nuclei.

roof n., n. fastigii.

n. ru'ber [NA], red n.; a large, well defined, somewhat cell mass, of reddish-gray hue in the fresh brain, located in the rostral mesencephalic tegmentum. The n. receives a massive projection from the contralateral half of the cerebellum by way of the cerebellar peduncle, and an additional projection from the contralateral motor cortex. Projections from the anterior interposus and motor cortex to the red nucleus are somatotopically organized. Its efferent connections are with the contralateral rhombencephalic reticular formation and spinal cord by way of the rubrospinal tracts. Rubrospinal fibers have somatotopically organized projections.

n. salivato'rius infe'rior [NA], inferior salivary n.; a group of ganglionic parasympathetic motor neurons located in the formation of the medulla oblongata dorsal to the n. ambiguus. Its axons leave the brain with the glossopharyngeal nerve to innervate the parotid gland by the intermediary of the submandibular ganglion; cells of the inferior and superior n. are seen overlapping in lateral regions of the reticular formation.
n. salivato'rius supe'rior [NA], superior salivary n.; a group of ganglionic parasympathetic motor neurons situated laterally to the inferior salivary n.; it governs secretion of the lacrimal, sublingual, and submaxillary glands by way of the nerve and the sphenopalatine and submandibular ganglia.
Schwalbe's n., n. vestibularis medialis. See nuclei vestibularis.

segmentation n., the compound n. in the impregnated formed by conjugation of the nuclei of the germ cell and sperm cell, or of the female and the male pronucleus.

semilunar n. of Flechsig, n. arcuatus thalami.

n. senso'rius principa'lis ner'vi trigem'ini [NA], n. sensorius nervi trigemini; the main sensory n. of the trigeminal ganglion.
n. senso'rius supe'rior ner'vi trigem'ini, n. sensorius nervi trigemini.

shadow n., a n. that has lost its pigment and staining property.
sole nuclei, an accumulation of skeletal muscle fibers near myoneural junction.

n. of solitary tract, n. tractus solitarius.

somatic n., macronucleus (2).

somatic motor nuclei, collective term indicating the motor nuclei innervating the tongue musculature (n. nervi hypoglossi), extraocular eye muscles (n. nervi abducentis, n. nervi trochlearis, n. nervi oculomotorii).

special visceral efferent (or motor) nuclei, branchiomotor nuclei, the head of the spermatozoon, which becomes the head of the ovum, after entering the ovum.

spherical n., n. globosus.

spinal n. of accessory nerve, n. spinalis nervi accessorii.
spinal n. of the trigeminus, n. tractus spinalis nervi trigemini.
n. spina'lis ner'vi accesso'rii [NA], spinal n. of the accessory nerve; a slender column of motor neurons extending longitudinally through the central part of the ventral horn of the upper cervical spinal cord, giving origin to the pars spinalis of the accessory nerve.

Spitzka's n., Perlia's n.